K003345 MAR 2 6 2001

510(k) SUMMARY

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

SUMMARY OF SAFETY AND EFFECTIVENESS FOR AOSept One-care Cleaning and Disinfecting Solution

1. **Submitter Information**

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley
Telephone No. 678-415-3897

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: AOSept One-care Cleaning and Disinfecting Solution

3. **Predicate Devices**

AOSept Disinfection System
Bausch & Lomb ReNu™ MultiPlus Multi-Purpose Solution

4. **Description of the Devices**

The AOSept One-care Cleaning and Disinfecting Solution is an aqueous solution containing hydrogen peroxide 3% (stabilized with phosphonic acid), sodium chloride, a phosphate buffer system and Pluronic 17R4 surfactant.

5. **Indications for Use**

AOSept One-care Cleaning and Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

6. **Description of Safety and Substantial Equivalence**

A series of preclinical and clinical studies were completed to demonstrate the substantial equivalence of AOSept One-care Cleaning and Disinfecting Solution to the predicate device(s). All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the solution is non-toxic and biocompatible, and is comparable to other currently marketed soft contact lens solutions. Results from all tests demonstrate the substantial equivalence to previously FDA approved predicate device.

Lens Compatibility Data:
There was no significant difference between AOSept One-care Cleaning and Disinfecting Solution and the control solution, with respect to optical and physical changes in the measured properties of the lenses.

Residual peroxide and Area under the Curve Study
The results of the study showed that the residual peroxide specification was met with test and the control solution. In addition, the area under the curve for AOSept One-care Cleaning and Disinfecting Solution was greater than that for the control solution.

In Vitro Cleaning Efficacy
This study was conducted to compare the protein cleaning efficacy of AOSept One-care Cleaning and Disinfecting Solution to ReNu Multiplus (rub/rinse regimen) and Optifree Express® with Aldox® (rub/rinse regimen). Results of the study showed that AOSept One-care Cleaning and Disinfecting

Solution without a rub or rinse removed is substantially equivalent to ReNu Multiplus with a rub/rinse and Optifree Express with a rub/rinse in terms of daily protein removal.

Proteolytic Activity
The results demonstrated that tablets dissolved in both the test and control solution at similar reduction times in lysozyme.

Cytotoxicity
A series of cytotoxicity studies were conducted to demonstrate the safety of AOSept One-care Cleaning and Disinfecting Solution. Results of the testing demonstrated that AOSept One-care Cleaning and Disinfecting Solution is as safe as the selected predicate devices.

Microbiological
A series of microbiological studies were conducted to demonstrate the microbial efficacy AOSept One-care Cleaning and Disinfecting Solution. These studies demonstrated that AOSept One-care Cleaning and Disinfecting Solution met the stand-alone criteria with organic load for disinfection. Additionally, the regimen test criteria was also meet for the regimen of the product.

Clinical Testing:

A three-month prospective, randomized, single masked, contralateral trial was conducted was conducted to support the substantial equivalence of AOSept One-care Cleaning and Disinfecting Solution. Sixty-six participants were enrolled in the trial and all wore lenses on a daily wear basis. The participant followed the manufacturer's instructions for the control product (including a rub and rinse) and followed the no rub / no rinse instructions provided with the test product

Results demonstrated minimal differences in discontinuations, adverse events, undesirable side effects, or severe grades/symptoms with the test or control product supports the safety of AOSept One-care without a rub and rinse. In addition, a greater number of symptoms and positive bio-microscopy findings in the ReNu Multiplus eye provide some evidence that AOSept One-care Cleaning and Disinfecting Solution was better tolerated by the eye over time.

With regards to the efficacy conclusion, the following findings were noted:

- Consistent overall preference for AOSept One-care Cleaning and Disinfecting Solution with increased preference over the duration of the trial.
- Greater hours of comfortable wear time were reported with AOSept One-care Cleaning and Disinfecting Solution.
- More stinging was reported with ReNu Multiplus.

7. **Substantial Equivalence Conclusion**
The pre-clinical and clinical data concludes that AOSept One-care Cleaning and Disinfection Solution (with a pre-rinse and without a rub) is substantially equivalent to Bausch & Lomb Renu Mulitplus Multi-purpose Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2001

Mr. Steven Dowdley, RAC
Senior Regulatory Associate
Global Regulatory Affairs
CIBA VISION Corporation
11460 Johns Creek Parkway
Duluth, GA 30097-1556

Re: K003345
Trade Name: AOSEPT One-Care Cleaning and Disinfecting Solution
(No rub for soft contact lenses replaced 30 days or less)
Regulatory Class: II
Product Code: 86 LPN
Dated: February 5, 2001
Received: February 7, 2001

Dear Mr. Dowdley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number: *This is a new 510 (k) Notification. (Number to be assigned)*

Device Name: AOSept One-care Cleaning and Disinfecting Solution

Indications for Use:
AOSept One-care Cleaning and Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or over-the-counter: ☒

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003345